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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/566,223

**Applicant(s)**

TYAGI ET AL.

**Examiner**

Angela M. Bertagna

**Art Unit**

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 June 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 117-120, 124 and 126-132 is/are pending in the application.
- 4a) Of the above claim(s) 130-132 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 117-120, 124 and 126-129 is/are rejected.
- 7) ☒ Claim(s) 117 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 3/8/10
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Status of the Application***

1. Applicant's response filed on June 3, 2010 is acknowledged. Claims 117-120, 124, and 126-132 are currently pending. In the response, Applicant amended claims 124, 128, and 129 and canceled claim 125. Claims 130-132 remain withdrawn from consideration as being drawn to a non-elected invention.

The following objections and rejections have been withdrawn in view of Applicant's amendment: (i) the objection to the specification, (ii) the objections to claims 124, 128, and 129, and (iii) the rejection of claims 125, 128, and 129 under 35 U.S.C. 112, first paragraph (new matter).

The rejections made previously under 35 U.S.C. 103(a) have been modified to account for the cancellation of claim 125. Applicant's arguments filed on June 3, 2010 regarding these rejections have been fully considered, but they were not persuasive for the reasons set forth below. Accordingly, this Office Action is made **FINAL**.

### ***Election/Restrictions***

2. This application contains claims 130-132 drawn to an invention nonelected with traverse in the reply filed on September 18, 2007. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the

currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Information Disclosure Statement***

3. Applicant's submission of an Information Disclosure Statement on March 8, 2010 is acknowledged. A signed copy is enclosed.

***Claim Objections***

4. Claim 117 is objected to because of the following informalities: This claim is missing a concluding period. Appropriate correction is required.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 117-120, 124, and 126 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chakravorty et al. (FEMS Microbiology Letters (2001) 205: 113-117; cited previously) in view of Jaber et al. (Tubercle and Lung Disease (1995) 76: 578-581; cited previously) and further in view of Herrnsstadt et al. (US 6,027,883; cited previously).

These claims are drawn to a method for processing clinical samples using a composition comprising three solutions.

Regarding claim 117, Chakravorty teaches a method comprising:

- (a) obtaining a clinical sample (page 114, section 2.1),
- (b) mixing 1.5 – 2 volumes of a first solution with the sample and homogenizing the sample (see page 114, section 2.2.1, where the IRS solution of Chakravorty comprises: 5 M GITC, 50 mM Tris-Cl, pH 7.5, 25 mM EDTA, 0.5% Sarcosyl, and 0.2 M  $\beta$ -mercaptoethanol),
- (c) centrifuging the homogenate to form a pellet (page 114, section 2.2.1),
- (d) washing the pellet obtained in step (c) with the first solution (page 114, section 2.2.2),
- (e) washing the pellet of step (d) with water (page 114, section 2.2.2), and
- (f) resuspending the water-washed pellet in solution A (*i.e.* a 10% suspension of a chelating resin), solution B (*i.e.* a 0.03% polyoxyethylene phenyl ether solution), and solution C (*i.e.* a 0.3% solution of polysorbate 20) (page 114, section 2.2.3).

Chakravorty further teaches that the supernatant obtained after step (e) is subjected to PCR amplification to amplify mycobacterial DNA (page 114).

Regarding claim 118, Chakravorty teaches homogenization for 30-60 seconds (page 114, column 1). This range of homogenization times lies within the claimed range of 20-120 seconds.

Regarding claim 119, Chakravorty teaches that the above process can be performed in approximately three hours (page 116, column 2).

Regarding claim 120, the 5 M concentration of GITC is about 4 M, about 5 M, and about 6 M, and the 0.2 M concentration of  $\beta$ -mercaptoethanol is about 0.1 M or about 0.2 M. This concentration of  $\beta$ -mercaptoethanol is also within the claimed range of 0.1-0.2 M. It is further noted that the intended use recitations “for processing samples for culture and smear”, “for processing of samples for culture, smear, and PCR”, and “samples processed for smear and PCR” have not been accorded patentable weight since they are intended use recitations that do not further limit the structural features of the positively recited method steps (MPEP 2111.02 II).

Regarding claim 124, Chakravorty teaches obtaining PCR-amplifiable DNA by adding 0.03% polyoxyethylene phenyl ether solution and heating the sample at 90°C for 40 minutes (page 115, column 1). This surfactant concentration lies within the claimed range of 0.01 - 0.1%. It is also noted that the method of Chakravorty is inherently capable of producing PCR-amplifiable RNA in addition to PCR-amplifiable DNA.

Regarding claim 126, Chakravorty does not specify that the samples were stored at about -20°C for a time up to two months. However, it is inherent that the samples can be processed for PCR, smear microscopy, and culture.

Chakravorty teaches the use of 5 M GITC in the first solution rather than 4-6 M GuHCl as required by claim 117. Also, Chakravorty does not teach adding sterile water to the homogenate as required by claim 117. Furthermore, Chakravorty also teaches that the above

sample processing method can be performed in approximately three hours (page 116, column 2) rather than the 1-2 hours required by claim 119.

Jaber teaches a method for isolating DNA from *Mycobacterium tuberculosis* (pages 578-579). The method of Jaber comprises the following steps: (1) cell lysis in 6 M GuHCl, 50 mM EDTA, 1 mM 2-mercaptoethanol, 0.05% Tween 80; (2) ethanol precipitation, (3) washing with lysis buffer, (4) phenol-chloroform and chloroform-isoamyl alcohol extraction, and (5) ethanol precipitation (see page 579).

Regarding claim 117, Jaber teaches that the chaotropic agent guanidinium hydrochloride, (GuHCl), “inactivates DNase and RNase, dissociates nucleoprotein, and disturbs cellular and subcellular structure, and its pH and ionic strength favor the native form of DNA (page 579, column 2).”

Herrnstadt teaches methods of isolating nucleic acids (see abstract and column 1, lines 50-61). Regarding claims 117-120, 124, and 126, Herrnstadt teaches that guanidine hydrochloride and guanidine isothiocyanate are chaotropic agents suitable for disrupting tissue samples for subsequent DNA or RNA isolation (column 1, lines 35-40).

It would have been *prima facie* obvious for one of ordinary skill in the art at the time of invention to substitute GuHCl for GITC in the sample processing method taught by Chakravorty. An ordinary artisan would have been motivated to do so, because as evidenced by the teachings of Jaber (see pages 579-580) and Herrnstadt (see column 1, lines 35-40), GuHCl and GITC were known in the art at the time of invention to be equivalents useful for the same purpose, namely cell lysis. As noted in MPEP 2144.06, the substitution of art-recognized equivalents known to be useful for the same purpose is *prima facie* obvious in the absence of unexpected results. In this

case, no evidence has been presented to suggest that the use of GuHCl is associated with unexpected results. Regarding step (d) in the method of claim 117, it also would have been *prima facie* obvious for one of ordinary skill in the art at the time of invention to dilute the homogenate prepared in the method resulting from the combined teachings of Chakravorty and Jaber using sterile water. An ordinary artisan would have been recognized that doing so would improve the method by decreasing the viscosity of the homogenate, and thereby, improving the centrifugation step. An ordinary artisan also would have recognized that the use of sterile water for the dilution step would have reduced the likelihood of contamination stemming from the presence of microorganisms in the water. It is also noted that dilution of the homogenate via the addition of sterile water constitutes an alteration of the concentration of the components of solution 1 used to prepare the homogenate. As noted in MPEP 2144.05, "Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical." In this case, no evidence has been presented to suggest that the claimed concentrations (*i.e.* those concentrations resulting from dilution of the homogenate with sterile water) are critical, and therefore, the claimed dilution step is *prima facie* obvious in view of the combined teachings of the cited references in the absence of secondary considerations.

Finally, regarding claims 118, 119, and 126, an ordinary artisan would have been motivated to optimize the homogenization time, the total processing time, and the sample storage conditions in order to achieve the desired results. Regarding the claimed range of homogenization times, attention is directed to MPEP 2144.05 I, which states that "[A] prior art reference that discloses a range encompassing a somewhat narrower claimed range is sufficient

to establish a *prima facie* case of obviousness." *In re Peterson*, 315 F.3d 1325, 1330, 65 USPQ2d 1379, 1382-83 (Fed. Cir. 2003). In this case, the range of 30-60 seconds disclosed by Chakravorty lies within the claimed range of 20-120 seconds, and therefore, a *prima facie* case of obviousness exists. An ordinary artisan also would have been motivated to minimize the time required for performance of the method in order to increase efficiency. An ordinary artisan also would have been motivated to store the samples in the manner required by claim 126 (*i.e.*, at about -20C for a time up to two months), since these sample storage conditions were conventional in the art at the time of the invention. Moreover, as noted in MPEP 2144.05, "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Routine optimization is not inventive, and no evidence has been presented to suggest that the selection of the claimed homogenization times, processing times, or sample storage conditions was other than routine or that the results should be considered to be unexpected compared to the prior art. Thus, the methods of claims 117-120, 124, and 126 are *prima facie* obvious in view of the combined teachings of the cited references.

7. Claims 127-129 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chakravorty et al. (FEMS Microbiology Letters (2001) 205: 113-117; cited previously) in view of Jaber et al. (Tubercle and Lung Disease (1995) 76: 578-581; cited previously) and further in view of Hermstadt et al. (US 6,027,883; cited previously) and further in view of GenBank Accession No. U22037 (March 1999; cited previously) and further in view of Marchetti et al.

(Journal of Clinical Microbiology (1998) 36(6): 1512-1517; cited previously) and further in view of Buck et al. BioTechniques (1999) 27(3): 528-536; cited previously).

The combined teachings of Chakravorty, Jaber, and Herrmstadt render obvious the methods of claims 117-120, 124, and 126, as discussed above.

Regarding claims 127-129, Chakravorty teaches using a set of primers designed from the *Mycobacterium tuberculosis* devR gene to amplify DNA isolated using the above method (page 114, column 2). However, Chakravorty does not teach amplification using two sets of primers, wherein each primer set targets the devR gene and produces amplification products of 308 bp and 164 bp as required by claims 127-129.

GenBank Accession No. U22037 teaches the complete nucleotide sequence of the *Mycobacterium tuberculosis* devR gene. The primers taught by Chakravorty are contained in this sequence and produce a 513 bp amplification product.

Marchetti teaches methods for amplifying *Mycobacterium tuberculosis* DNA by PCR (see abstract and page 1513). Marchetti compared the sensitivity of four different PCR primer pairs and determined that the use of primers designed to amplify shorter targets resulted in more sensitive detection than primers designed to amplify longer targets (see abstract and pages 1514-1515). Marchetti further stated, "PCR3 and PCR4, whose final amplification products are 106 and 123 bp long, respectively, showed the best results in terms of sensitivity compared to those of PCR1 and PCR2, which amplify longer fragments (223 and 143 bp, respectively). This suggests the need to choose the correct primers, with those amplifying relatively shorter DNA sequences, which are thus less prone to fragmentation, being favored (page 1515, column 2)."

Buck analyzed the effect of primer design strategy on the performance of DNA sequencing primers. Specifically, Buck invited primer submissions from a number of labs (39) (page 532, column 3), with 69 different primers being submitted (see page 530, column 1). Buck also tested 95 primers spaced at 3 nucleotide intervals along the entire sequence at issue, thereby testing more than 1/3 of all possible 18 mer primers on the 300 base pair sequence (see page 530, column 1). When Buck tested each of the primers selected by the methods of the different labs, Buck found that every single primer worked (see page 533, column 1). Only one primer ever failed, No. 8, and that primer functioned when repeated. Further, every single control primer functioned as well (see page 533, column 1). Buck expressly states “The results of the empirical sequencing analysis were surprising in that nearly all of the primers yielded data of extremely high quality (page 535, column 2).” Therefore, Buck provides direct evidence that all primers would be expected to function, and in particular, all primers selected according to the ordinary criteria, however different, used by 39 different laboratories. It is particularly striking that all 95 control primers functioned, which represent 1/3 of all possible primers in the target region. This clearly shows that the selection and use of primers in primer extension methods yields predictable results.

It would have been *prima facie* obvious for one of ordinary skill in the art at the time of invention to utilize any set of primer pairs designed from the known *Mycobacterium tuberculosis* devR gene to amplify DNA isolated by the method resulting from the combined teachings of Chakravorty, Jaber, and Herrnstadt. Since Marchetti taught that the use of primers designed to amplify short targets in the *Mycobacterium tuberculosis* genome resulted in increased sensitivity (pages 1514-1515), an ordinary artisan would have been motivated to design primer pairs

targeting sequences shorter than the 513 bp region targeted by Chakravorty. An ordinary artisan would have had a reasonable expectation of success designing these primers since the complete devR gene sequence was known in the art at the time of invention as evidenced by GenBank Accession No. U22037. An ordinary artisan also would have had a reasonable expectation of success in using the primers in the method resulting from the combined teachings of Chakravorty, Jaber, and Herrnstadt, since Buck demonstrated that essentially all primers were capable of an equivalent degree of extension when hybridized to a complementary target. Therefore, absent any secondary considerations, the claimed methods are *prima facie* obvious in view of the combined teachings of Chakravorty, Jaber, Herrnstadt, Marchetti, GenBank Accession No. U22037, and Buck.

Attention is also directed to *KSR Int'l Co. v. Teleflex Inc.* (550 U.S. \_\_\_, 127 S. Ct. 1727 (2007)) where the Supreme Court determined that “a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under § 103 (*KSR*, 550 U.S. at \_\_\_, 82 USPQ2d at 1397).”

In the instant case, as discussed above, an ordinary artisan would have been motivated to apply the teachings of Marchetti regarding dependence of PCR sensitivity on target length to the method resulting from the combined teachings of Chakravorty, Jaber, and Herrnstadt. The complete nucleotide sequence of the *Mycobacterium tuberculosis* devR gene, which is disclosed in GenBank Accession Number U22037, presented the ordinary artisan with a finite number of possible primers for amplification. Then, since Buck taught that a large number of primers

designed to detect the same target functioned reasonably well, an ordinary artisan would have expected predictable results, and thus would have had a reasonable expectation of success, when testing the finite number of possible amplification primers suggested by applying the teachings of Marchetti to the devR gene targeted by Chakravorty. Thus, the methods of claims 127-129 are *prima facie* obvious over the cited references in the absence of secondary considerations.

### ***Response to Arguments***

8. As noted above, the objection to the specification, objections to claims 124, 128, and 129, and the rejection of claims 125, 128, and 129 under 35 U.S.C. 112, first paragraph (new matter) have been withdrawn in view of Applicant's amendment. Accordingly, Applicant's arguments filed on June 3, 2010 regarding these objections and rejections have been considered, but they are moot in view of the withdrawal of the rejections and objections.

Applicant's arguments filed on June 3, 2010 regarding the rejections made previously under 35 U.S.C. 103(a) have been fully considered, but they were not persuasive.

Regarding the rejection of claims 117-120, 124, and 126 under 35 U.S.C. 103(a) as being unpatentable over Chakravorty in view of Jaber and further in view of Herrnstadt, Applicant argues that the purpose of the claimed USP solution is to lyse and remove all cells except for mycobacteria in a sample, which remain viable and can be used to culture the mycobacteria, in smear microscopy, or in PCR after DNA isolation (page 9). Applicant argues that the cited references are directed to DNA isolation methods, and, accordingly, when they are considered as a whole, they do not teach or suggest obtaining viable mycobacteria in the pellet produced by the method of independent claim 117 (pages 9-10). Applicant also argues that there is no reason for

the ordinary artisan to expect that one could isolate viable mycobacteria based on the combined teachings of the cited references (page 10).

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., obtaining a pellet containing viable mycobacteria) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). In this case, claims 117-119 and 124 do not require this feature, and, accordingly, Applicant's argument was unpersuasive.

It is noted that claims 120 and 124 require that the samples are capable of being used in smear microscopy or culture methods. However, this feature does not appear to result in a structural difference between the claimed methods and the methods suggested by the combined teachings of the cited references. As noted in MPEP 2111, an intended use recitation must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In this case, as discussed above, the combined teachings of the cited references suggest the claimed method, and, since there is no apparent difference between them, it is inherent that the resulting pellets contain viable mycobacteria suitable for use in smear microscopy or culture methods.

Finally, it is noted that the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227

USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). In this case, as discussed above, the ordinary artisan would have been motivated to substitute one chaotropic agent for another when practicing the method of Chakravorty since the GITC used in the method of Chakravorty and the GuHCl used in the method of Jaber were each known in the art to be useful chaotropic agents for disrupting cells and tissues. Attention is also directed to MPEP 2144, which states, "The reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve a different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant." See, e.g., *In re Kahn*, 441 F.3d 977, 987, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006) (motivation question arises in the context of the general problem confronting the inventor rather than the specific problem solved by the invention); *Cross Med. Prods., Inc. v. Medtronic Sofamor Danek, Inc.*, 424 F.3d 1293, 1323, 76 USPQ2d 1662, 1685 (Fed. Cir. 2005) ("One of ordinary skill in the art need not see the identical problem addressed in a prior art reference to be motivated to apply its teachings."); *In re Linter*, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972); and *In re Dillon*, 919 F.2d 688, 16 USPQ2d 1897 (Fed. Cir. 1990), cert. denied, 500 U.S. 904 (1991).

Since Applicant's arguments were not persuasive, the rejection of claims 117-120, 124, and 126 under 35 U.S.C. 103(a) as being unpatentable over Chakravorty in view of Jaber and further in view of Hermstadt has been maintained with modifications to address the cancellation of claim 125.

Regarding the rejection of claims 127-129 under 35 U.S.C. 103(a) as being unpatentable in view of the combined teachings of Chakravorty, Jaber, Hermstadt, GenBank Accession No. U22037, Marchetti, and Buck, Applicant argues that these claims depend from claim 117, which

is not rendered obvious by the combined teachings of the primary combination of references (*i.e.*, Chakravorty, Herrnstadt, and Jaber), and that the additional secondary references cited in the rejection do not overcome the deficiencies present in the primary combination of references (see page 10). This argument was not persuasive, because as discussed above, the combined teachings of Chakravorty, Jaber, and Herrnstadt render obvious the methods of claims 117-120, 124, and 126. Accordingly, the rejection has been maintained.

### ***Conclusion***

9. No claims are currently allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANGELA BERTAGNA whose telephone number is (571)272-8291. The examiner can normally be reached on M-F, 7:30 - 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Angela M Bertagna/  
Examiner, Art Unit 1637

/Young J Kim/  
Primary Examiner, Art Unit 1637